OCT - 4 2001

510(k) Summary

K010396 p.1/2

General Information:

This 510(k) is to provide notification of substantial equivalence for the Cardionetics C.Net 2100 Single Channel ECG Ambulatory Monitor, which is substantially equivalent to previously marketed devices intended for ambulatory cardiac monitoring.

Submitted by:
Cardionetics Ltd.
Centaur House
Ancells Business Park
Fleet
Hampshire
GU51 2UJ
United Kingdom

Contact Person: Neil McLachlan

Date prepared: February 8, 2001

Classification: Class II

Trade Name: C.Net 2100

Common Name: Event Recorder

Predicate Devices: Novacor S.A.R.Test Evolution Event Recorder
MSB Ltd. Ecotabs

Indication for Use: The C.Net 2100 Monitor is intended for in-context monitoring of adult patients where symptoms occur infrequently or where resting ECG monitoring is unlikely to capture symptomatic or asymptomatic abnormal rhythm events.

Its use includes assessing symptoms (including palpitations, dizzy spells, paroxysmal light-headedness, and pounding of the heart) that may relate to disturbances of the heart.

Where it is clinically appropriate, the C.Net 2100 Monitor can assist in ongoing monitoring of the frequency of abnormal rhythm events in patients receiving anti-arrhythmic medication or rehabilitation therapy.

Description:

Designed for ease of use, the C.Net 2100 is quick and simple to set up and comfortable to wear. It is compact and can be worn in a pouch on a belt around the waist or in a jacket pocket.

The C.Net 2100 has:

- a standard 3 electrode application
- a double-use button for:
- event-recording up to 10 events per 24 hour period
- printing/downloading the analysis
- one socket for both the electrode lead and the printer lead plug
- an on/off switch.

Simple to use, the electrode pads are applied to three routine places on the chest wall by a nurse or physician. The unit is switched on and allowed to synchronize to the patient's ECG. No programming is necessary.

For event recording, the button on the C.Net 2100 monitor is pressed. This is the only interaction of the patient with the unit.

At the end of the monitoring period the C.Net 2100 is removed from the patient, the patient electrode lead disconnected and the unit is connected to a printer using the Smart Printing Cable. The Summary Report, containing the classified cardiac data for the patient, is printed, allowing a preliminary assessment of the data to be quickly performed by a physician.

When used as indicated in the labeling no special skills are required to operate the unit and the quality of data is not dependent on special operator skills.

The unit cannot be programed by the user or the patient.

Testing:

The C.Net 2100 complies with BS EN60601-1 (IEC 601-1) Electrical Safety standard, BS EN 60601-1-1-3 (IEC601-1-1-3) standard and ANSI EC38:1998 performance standard.

Summary of Substantial Equivalence:

The results of electrical safety and software validation tests indicate that the C.Net 2100 performs in a manner substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Cardionetics, Ltd.
c/o Barry Sall, RAC
Senior Regulatory Consultant
PARAXEL International Corporation
195 West Street
Waltham, MA 02451

Re: K010396
Trade Name: Cardionetics C.Net 2100 Single Channel ECG Ambulatory Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, ambulatory, with analysis algorithm
Regulatory Class: Class II (two)
Product Code: MLO
Dated: July 6, 2001
Received: July 9, 2001

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

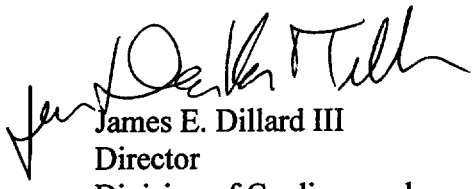
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010396

Device Name:

Indications For Use:

The C.Net 2100 Monitor is intended for in-context monitoring of adult patients where symptoms occur infrequently or where resting ECG monitoring is unlikely to capture symptomatic or asymptomatic abnormal rhythm events.

Its use includes assessing symptoms (including palpitations, dizzy spells, paroxysmal light-headedness, and pounding of the heart) that may relate to disturbances of the heart.

Where it is clinically appropriate, the C.Net 2100 Monitor can assist in ongoing monitoring of the frequency of abnormal rhythm events in patients receiving anti-arrhythmic medication or rehabilitation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010396

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional format 1-2-96)